

Attorney Dkt. No. 51275/149

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re: application of:

Theoharis C. Theoharides

Filing date: 03/20/2004

Serial No.: 10/811,828

Priority from copending PCT/US02/00476, filed 01/03/2002,
copending USSN 09/771,669, filed 01/30/2001, and USSN 09/056,707, filed
4/8/1998, now USPN 6,689,748, issued 2/10/2004

For: Composition For Protection Against Superficial Vasodilator Flush Syndrome

APR 12 2007

Group Art Unit: 1655

Examiner: Patricia Leith

Response to Notice of Abandonment

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450
Mail Stop: Non-fee Amendment

Sir:

In an Action mailed 04/10/2007, the Examiner issued a Notice of Abandonment for an alleged failure to respond to Examiner's 08/28/2006 Office Action.

The Examiner appears not to be aware that the Office Actions of 08/28/2006 and 05/04/2006, both concerning a restriction requirement, were responded to by a Petition to the Director, dated 10/09/2006. A copy of the Petition and acknowledgement of receipt by the Office are enclosed. This Petition has not yet been acted upon. Until the Director adjudicates the issue, it is the undersigned's opinion that a response to the 08/28/2006 Office Action is held in obeyance. Please correct me if my opinion is incorrect.

Respectfully submitted,

Dr. Melvin Blecher
Attorney-at-Law
Registration No. 33,649

04/12/2007

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<p>10/09/2006 09:22 2023628404 MBIPLAW PAGE 03</p> <p>Attorney Dkt No. 51278149</p> <p>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE VIA FACSIMILE</p> <p>In re: application of: Theofanis C. Theofanidis Filing date: 03/20/2004 Serial No.: 10/811,822 Priority from co-pending PCT/US02/00476, filed 01/03/2002, co-pending USBN 09/771,668, filed 01/03/2001, and USBN 09/086,707, filed 04/19/98, now USPN 6,889,748, issued 2/10/2004 For: Composition For Protection Against Superficial Vasodilator Flush Syndrome</p> <p><u>Petition Under 37 CFR 1.144</u></p> <p>Commissioner for Patents Box 1450 Alexandria, VA 22213-1450 Mail Stop: TC1800 Director Bruce Kellak</p> <p>Sir:</p> <p>Applicant is petitioning for reversal of the Examiner's restriction requirement initially mailed 05/04/2006, and maintained in her Office Action mailed 08/28/2006.</p> <p>The claims in question are set forth below. All of the claims are the original claims.</p> <p>40. A composition for protecting a subject from the inflammatory disease superficial vasodilator flush syndrome, said composition comprising a non-sulfated proteoglycan, olive kernel extract, a Flavonoid compound, bitter willow bark extract, and, optionally, cyproheptadine or azatidine.</p> <p>41. The composition of claim 40, wherein said proteoglycan is sulfated chondroitin sulfate.</p> <p>42. The composition of claim 40, wherein said flavonoid compound is quercetin, myricetin or genistein.</p> <p>43. The composition according to claim 1, wherein said inflammatory disease is superficial vasodilation flush syndrome, said composition comprising 50 mg non-</p>

PAGE 40*RCVD AT 10:22 AM 10/10/06 [Eastern Daylight Time] *SVR:USPTO-EFXRF-37 *DNIS:2738300 *CSID:2023628404 *DURATION (mm:ss):01:48

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
VIA FACSIMILE**

In re: application of:

Theoharis C. Theoharides

Filing date: 03/20/2004

Serial No.: 10/811,828

**Priority from copending PCT/US02/00476, filed 01/03/2002,
copending USSN 09/771,669, filed 01/30/2001, and USSN 09/056,707, filed
4/8/1998, now USPN 6,689,748, issued 2/10/2004**

For: Composition For Protection Against Superficial Vasodilator Flush Syndrome

Group Art Unit: 1655

Examiner: Patricia Leith

Petition Under 37 CFR 1.144

Commissioner for Patents

Box 1450

Alexandria, VA 22313-1450

Mail Stop: TC1600 Director Bruce Kisliak

Sir:

**Applicant is petitioning for reversal of the Examiner's restriction
requirement initially mailed 05/04/2006, and maintained in her Office Action
mailed 08/28/2006..**

**The claims in question are set forth below. All of the claims are the original
claims.**

**40. A composition for protecting a subject from the inflammatory disease
superficial vasodilator flush syndrome, said composition comprising a non-
bovine heavily sulfated proteoglycan, olive kernel extract, a flavonoid compound,
bitter willow bark extract, and, optionally, cyproheptadine or azatadine.**

**41. The composition of claim 40, wherein said proteoglycan is sulfated
chondroitin sulfate.**

**42. The composition of claim 40, wherein said flavonoid compound is quercetin,
myricetin or genistein.**

**43. The composition according to claim 1, wherein said inflammatory disease is
superficial vasodilation flush syndrome, said composition comprising 50 mg non-**

bovine chondroitin sulfate; olive kernel extract, 150-600 mg; 150-350 mg quercetin; 5% by weight bitter willow bark extract; and, optionally, 4 mg cyproheptadine or azatadine, administered daily.

44. A method of protecting against superficial vasodilator flush syndrome, comprising the oral administration of the composition of claim 40 or claim 43.

45. The composition of claim 1, wherein said syndrome is selected from the group consisting of carcinoid-induced flush, niacin-induced flush, mesenteric fraction syndrome-induced flush, and serotonin syndrome-induced flush.

As to the flavonoid component of generic claim 1, contrary to the examiner's assertion, all flavonoids have the same basic three-ring structure shown as Fig. 1 in applicant's traversal of 06/21/2006. The flavonoid species quercetin, myricetin and genestelin listed in claim 42 are merely claimed members of the same family. Looking at Fig. 2, also of record, it can be seen that quercetin and myricetin differ from each other only by a small functional group, namely, a hydroxyl group at R2. Looking at Fig. 3, also of record, it can be seen that genestelin has the same empirical formula as quercetin. All known members of the family of flavonoids have, contrary to the examiner's assertion, the same pharmacological, and differ only in relative strength. The examiner has shown no evidence to the contrary. Hence, applicant submits that this restriction requirement was made in error, and petitions the Director to reverse it.

The examiner has also ruled that the heavily sulfated proteoglycan component of composition claim 40 is too broad, and has ruled that applicant must limit this component to the chondroitin sulfate recited in claim 41. The applicant traversed by showing that chondroitin sulfate is merely one of a family of molecules more accurately called "glycosaminoglycans" because one of the two sugars is always an amino sugar, e.g., N-acetylglucosamine. Other members of this family are listed and described in the accompanying e-articles with the URLs of <http://biol.lancs.ac.uk/gig/pages/pgnpage.htm> and <http://biol.paisley.ac.uk/courses/stfunmac/glossary/proteoglycan.htm>. All

sulfated proteoglycans are generally known in the art to exhibit similar properties, that include cartilage formation and joint lubrication. In the present invention, sulfated proteoglycans are shown to have anti-inflammatory effects. Thus, a search for "sulfated proteoglycans" will uncover chondroitin sulfate and other glycosaminoglycans suitable for practicing this invention. Applicant submits that it would be appropriate for the Director to withdraw this restriction requirement.

The Director is also respectfully reminded that there is an Office Action pending in this application.

10/9/2006

Respectfully submitted,


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